Appendix 2 - Amendments to Claims

1. (Amended) A method of reducing mortality associated with heart failure, for improving the oxygen consumption, for improving the quality of life or for improving exercise tolerance in a black patient comprising administering to the black patient a therapeutically effective amount of at least one hydralazine compound of Formula (I), or a pharmaceutically acceptable salt thereof, and at least one of isosorbide dinitrate and isosorbide mononitrate,

wherein the hydralazine compound of Formula (I) is:

(I)

wherein a, b and c are each independently a single or a double bond; R_1 and R_2 are each independently a hydrogen, an alkyl, an ester or a heterocyclic ring; R_3 and R_4 are each independently a lone pair of electrons or a hydrogen, with the proviso that at least one of R_1, R_2, R_3 and R_4 is not a hydrogen.

2. (Amended) The method of claim 1, wherein the black patient has a less active [renin-angiotension] renin-angiotensin system relative to a white patient.

17. (Amended) The method of claim 15, wherein the tablet is in the form of a sublingual tablet, a sustained-release tablet or a chewable tablet.

18. (Amended) The method of claim 1, wherein the at least one hydralazine compound and the at least one of isosorbide dinitrate and isosorbide mononitrate are administered to the black patient as components of the same composition.

19. (Amended) The method of claim 1, wherein the at least one hydralazine compound and the at least one of isosorbide dinitrate and isosorbide mononitrate are administered to the black patient as separate components.

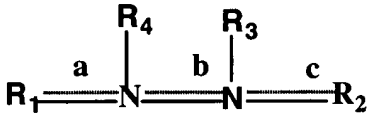
20. (Amended) The method of claim 19, wherein the at least one hydralazine compound and the at least one of isosorbide dinitrate and isosorbide mononitrate are administered to the black patient as separate components at about the same time.

33. (Amended) The method of claim 32, further comprising treating the black patient orally with digoxin in an amount sufficient to achieve a blood serum concentration of digoxin of at least about 0.7 nanograms per milliliter and an effective edema managing amount of at least one pharmaceutically acceptable diuretic selected from [the group consisting of] a thiazide, a ethacrynic acid, a furosemide, a spironalactone and a triamterene.

35. (Amended) The method of claim 32, further comprising treating the black patient with at least one compound used to treat a cardiovascular disease.

39. (Amended) A kit comprising at least one hydralazine compound of Formula (I), or a pharmaceutically acceptable salt thereof, and at least one of isosorbide dinitrate and isosorbide mononitrate,

wherein the hydralazine compound of Formula (I) is:



(I)

wherein a, b and c are each independently a single or a double bond; R_1 and R_2 are each independently a hydrogen, an alkyl, an ester or a heterocyclic ring; R_3 and R_4 are each independently a lone pair of electrons or a hydrogen, with the proviso that at least one of R_1, R_2, R_3 and R_4 is not a hydrogen, and

written instructions in a form prescribed by a governmental agency regulating the manufacture, use or sale of pharmaceuticals or biological products, to a black patient.

42. (New) The method of claim 1, wherein the black patient is not as responsive to an angiotensin-converting enzyme inhibitor relative to a white patient.

43. (New) The method of claim 1, wherein the black patient has a deficient nitric oxide generation system.

44. (New) The method of claim 32, wherein the black patient is not as responsive to an angiotensin-converting enzyme inhibitor relative to a white patient.

45. (New) The method of claim 32, wherein the black patient has a deficient nitric oxide generation system.

46. (New) The method of claim 32, wherein the black patient has a less active renin-angiotensin system relative to a white patient.

47. (New). The method of claim 32, wherein the black patient has hypertension.

48. (New) A method of reducing mortality associated with heart failure in a black patient comprising administering to the black patient a therapeutically effective amount of hydralazine or a pharmaceutically acceptable salt thereof and isosorbide dinitrate.

49. (New) A method of reducing mortality associated with heart failure in a black patient with hypertension comprising administering to the black patient with hypertension a therapeutically effective amount of hydralazine or a pharmaceutically acceptable salt thereof and isosorbide dinitrate.

50. (New) A kit comprising hydralazine or a pharmaceutically acceptable salt thereof, isosorbide dintrate, and written instructions in a form prescribed by a governmental agency regulating the manufacture, use or sale of pharmaceuticals or biological products, for administration to a black patient.

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Appendix 4 - Amendments to Specification

Please amend the paragraph in the specification at page 11, lines 1-5, as follows:

In the present invention, the preferred hydralazine compound is hydralazine, which is preferably administered in the form of a pharmaceutically acceptable salt and most preferably in the form of hydralazine hydrochloride. [Hyralazine] Hydralazine hydrochloride is commercially available from, for example, Lederle Standard Products, Pearl River, NY; and Par Pharmaceuticals Inc., Spring Valley, NY.

Please amend the paragraph in the specification at page 11, lines 10-12, as follows:

Isosorbide mononitrate is commercially available, for example, under the trade names IMDUR® (A. B. Astra, Sweden); MONOKET® (Schwarz Pharma, Milwaukee, WI); and ISMO® (Wyeth-Ayerst [company, Philadephia,] Company, Philadelphia, PA).

Please amend the paragraph in the specification at page 14, lines 17 to 25, as follows:

While individual needs may vary, determination of optimal ranges for effective amounts of the compounds and/or [compositons] compositions is within the skill of the art. Generally, the dosage required to provide an effective amount of the compounds and compositions, which can be adjusted by one of ordinary skill in the art, will vary depending on the age, health, physical condition, sex, diet and medical condition of the patient, the severity of the cardiovascular disease, the route of administration, pharmacological considerations such as the activity, efficacy, pharmacokinetic and toxicology profiles of the particular compound used, whether a drug delivery system is used, and whether the compound is administered as part of a drug combination.

Please amend the paragraph in the specification at page 23, lines 21-25, as follows:

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Prior studies in hypertension have suggested that reduced responsiveness to ACE inhibitors may be attributed to a lower PRA in the black [population] population. Indeed, the differential benefit in V-HeFT II of ACE inhibitor therapy in whites compared to blacks was particularly prominent in those with a prior history of hypertension in whom PRA was significantly lower in blacks than in whites.

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